

REMARKS

Claims 1-34 are pending in the application and are currently rejected. Claims 1-9, 12-20, 29 and 30 have been amended, and claims 10 and 11 have been withdrawn. In light of the amendments and remarks herein, reconsideration of claims 1-9 and 12-34 is respectfully requested.

Amendments to the Specification

The Specification has been amended to address the Examiner's objections. No new matter has been added to the Specification.

Amendments to the Claims

While Applicants believe that the previously presented claims are patentable over all of the art cited in the Office Action as well as all other references submitted by Applicants, the claims have nonetheless been amended as follows in order to expedite the allowance of the claims. The amendments are therefore made without prejudice or disclaimer, and Applicants reserve the right to pursue the original scope of the claims as provided prior to the cancellation or amendments, such as through continuation practice.

Claim 1 is amended to claim an apparatus having a set of bristles that are configured to transmit therapeutic radiation, in addition to the transmission of radiation to other tissue in the oral cavity as originally claimed. Support for the amendment is found, among other places, in paragraph 012 of the application, which states:

The oral applicator can optionally include a plurality of bristles that are substantially transparent to phototherapeutic radiation within at least one wavelength range. In one embodiment, the bristles can act as waveguides via optical coupling to a radiation emitter to receive and propagate radiation therefrom. The bristles can alternatively act to diffuse light based on an enhanced shape and/or a scattering agent disposed in the bristles to diffuse radiation.

Claims 2-8 and 11-13 are amended to conform the dependent claims to the language of Claim 1.

Claim 14 is amended to clarify the relative direction of the shape being claimed.

Claims 15-17 are amended to conform the dependent claims to the language of Claim 1.

Claim 18 is amended to claim bristles that are optically coupled to a second emitter.

Claim 19 is amended to address the Examiner's objection to the claim, and to correct an inconsistency in claim terms.

Claim 20 is amended to correct the dependency from Claim 19 to Claim 1, which corrects the antecedent basis and structural issue addressed by the Examiner.

Claims 29 and 30 are amended to provide requisite structure.

As such, the amendments to claims 1-8, 12-20, 29 and 30 do not add new matter.

Double Patenting

The Examiner provisionally rejected claims 1-4 and 10-18 and 20 based on obviousness-type double patenting as being unpatentable over claims 10-20 of copending U.S. Patent Application No. 10/776686 (the "'686 Application").

The differences between Claim 1 in the present application and Claim 1 of the '686 Application are not obvious. The differences are due to a distinction in the kind of each claimed inventions that renders each patentably distinct. For example, Claim 1 of the present application recites a "plurality of optically transmissive bristles" that are "coupled to the body" while also reciting "at least one radiation emitter coupled to the body to irradiate with phototherapeutic radiation a portion of the oral cavity other than tissue in contact with the bristles." On the other hand, Claim 1 of the '686 Application, from which Claims 10-20 depend, recites "at least one radiation emitting element coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation along multiple directions." These two independent claims are directed to two distinct concepts that are not obvious in light of each other. The present application claims a device that is capable of treating two different tissues, e.g., gums and teeth, with therapeutic radiation, while brushing one of those tissues, e.g., the teeth, using optically

transmissive bristles, while Claim 1 of the '686 Application claims a device that is designed to emit radiation in multiple directions.¹ Claims 10-20 of the '686 Application are not drawn to the same invention.

Claims 2-4 and 11-18 and 20 of the present invention are patentably distinct for the same reasons that Claim 1 is patentably distinct.

However, to the extent that the present invention is capable of emitting therapeutic radiation in multiple directions and assuming that otherwise allowable claims in the '686 Application would claim the same subject matter as the claims of the present Application, the Applicant's are prepared to either file a terminal disclaimer and/or submit an appropriate amendment to the claims of each application to overcome any remaining obviousness-type double patenting objection.

The Examiner also provisionally rejected claims 1-5, 8-11, 14, 16-18 and 20 based on obviousness-type double patenting as being unpatentable over claims 11-23 of copending Application No. 10/777022 (the "'022 Application").

The differences between Claim 1 in the present application and Claim 1 of the '022 Application are not obvious. The differences are due to a distinction in the kind of each claimed inventions that renders each patentably distinct. Again for example, Claim 1 of the present application recites a "plurality of optically transmissive bristles" that are "coupled to the body" while also reciting "at least one radiation emitter coupled to the body to irradiate with phototherapeutic radiation a portion of the oral cavity other than tissue in contact with the bristles." On the other hand, Claim 1 of the '022 Application, from which claims 11-23 depend recites "at least one radiation emitter coupled to the body to irradiate a portion of the oral cavity with phototherapeutic radiation in *at least two separate spectral bands*." These two independent claims are directed to two distinct concepts that are not obvious in light of each other. As discussed above, the present application claims a device that is configured to treat one tissue, e.g., gums, with radiation, while brushing and irradiating a second tissue, e.g., the teeth, with

¹ Unless specifically noted otherwise, any use of examples in this response is intended to be exemplary only and is not intended to limit the scope of any present claim or any claim that may issue from this application.

bristles. The claims of the '022 Application are directed to a device that is capable of irradiating tissue in the oral cavity using distinct spectral bands to, e.g., "treat the same conditions more effectively or to treat two different conditions." (See Application ¶ 086.) Dependent claims 11-23 of the '022 Application do not render Claim 1 in the present application obvious, because those claims also include the patentably distinct limitations of Claim 1 of the '022 Application.

Claims 2-5, 8-9, 14, 16-18 and 20 of the present invention are patentably distinct for the same reasons that Claim 1 is patentably distinct. (Claims 10 and 11 have been cancelled.)

However, assuming that otherwise allowable claims in the '022 Application would claim the same subject matter as the claims of the present Application, the Applicant's are prepared to either file a terminal disclaimer and/or submit an appropriate amendment to the claims of each application to overcome any remaining obviousness-type double patenting objection.

Claim Rejections - 35 U.S.C. § 112

Claims 14 and 20 were rejected as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Applicants have amended those claims accordingly.

Claim Rejections - 35 U.S.C. § 102

Claims 1-4, 7-8, 10-18, 23, 29-30, 32 and 34 are rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,862,771 to Muller (herein "Muller"). These claims are novel, however, because Muller fails to teach or suggest the elements recited in the amended claims.

Claim 1 recites an apparatus for treating tissue in an oral cavity comprising a body, a plurality of bristles coupled to the body, and "at least one radiation emitter coupled to the body to irradiate with phototherapeutic radiation a portion of the oral cavity other than tissue in contact with the bristles." In contrast, Muller is directed to "a toothbrush head suitable to direct incident radiation toward a surface of a tooth and to collect emitted radiation from the surface of the

tooth.” (See Muller, Abstract.) Muller teaches irradiating the tooth itself, and does not teach irradiating other tissues. Muller is silent as to the treatment of tissues other than a tooth. Furthermore, as the Examiner noted at page 4 of the Office Action, Muller discloses a device that radiates teeth “in a direction parallel to the bristles, either between the bristles or through the optically transparent bristles.”

Consistent with those limitations, Muller discloses a device having a limited purpose. Specifically, Muller discloses using the device as a sensor to detect biological deposits on the tooth. For example, Muller states:

In use the toothbrush of the invention is used to brush the user's teeth, thereby aligning the bristle face 3 so that it faces the tooth surface at a convenient distance. The control 176 is operated, and incident radiation is directed in the direction 5 from the source 173, being reflected by dichroic mirrors 179, 180 onto a tooth surface using the toothbrush head 1 of this invention, for example via the filaments 113. Fluorescence radiation is emitted from the tooth surface, either from biological deposits such as plaque or from a deposit-free tooth surface or from both. This emitted radiation is collected by the head 1, e.g. again e.g via filaments 113 and directed back as described above to the detector 174, being transmitted through the dichroic mirror 180. An electrical signal is generated by the detector 174 and is processed by the processing device 177. The processing device 177 operates the signaling means 178 to indicate to the user the presence or absence of biological deposit.

(Muller Col. 14:59 to 15:8.)

On the other hand, the Applicants claim a device that is capable of treating two different tissues in the oral cavity. Specifically, the Applicants disclose and claim a device that has bristles “configured to transmit therapeutic radiation” and that can “irradiate with phototherapeutic radiation a portion of the oral cavity other than tissue in contact with the bristles.”

Thus, Muller does not anticipate Claim 1, and Claim 1 is novel and patentable. Similarly, Claims 2-4, 7-8, 12-18, 23, 29-30, 32 and 34, which are dependent on Claim 1, are patentable for the same reasons.

Further, Muller does not disclose the elements of Claim 15, i.e., bristles shaped to transmit radiation upon contact between the bristles and a portion of the oral cavity. Applicants teach using bristle shape to contain radiation using the principle of total internal reflection. Specifically, at paragraph 92, the specification states:

To further assist with transfer of the optical radiation to tissue, the refractive index of the bristle tip and target tissue can be matched. For example, because of the difference between the refractive index of air and the bristle, the bristle 14 can mostly contain the optical radiation by internal reflection. Only when the bristle touches tissue, is there an increase in the amount of optical radiation released.

Muller does not teach this concept. Rather, Muller teaches a core that uses the concept of total internal reflection in the head of the device, but, consistent with the disclosed purposes and operation of Muller's device, Muller never applies this teaching to prevent the emission of radiation through the bristles. (Muller Col. 11:25-35 and, e.g., FIG. 6.) Muller does not require or teach using total internal reflection to prevent the emission of radiation from the bristles when the bristles are not in contact with tissue. In the primary embodiment of Muller, the radiation is not transmitted through the bristles at all, but is instead emitted directly from the head and around the bristles.

Claims 1, 2, 7, 19 and 32 are rejected under 35 U.S.C. §102(b) as being anticipated by PCT Application Number WO 95/10243 to Mendes et al. (herein "Mendes"). These claims are novel, however, because Mendes fails to teach or suggest the elements recited in the amended claims.

Specifically, Mendes fails to teach or suggest a plurality of bristles that are configured to transmit therapeutic radiation, as required in Claim 1. As noted in Mendes, with reference to FIG. 1, the LEDs 110 that are used to emit radiation are not optically coupled to the bristles 104. The LEDs 110 are located on either side of the bristles 104 in one embodiment, and are surrounded by the bristles 104 in another embodiment. (Mendes at 6:16-36.)

Thus, Mendes does not anticipate presently amended Claim 1, and Claim 1 is novel and patentable. Similarly, Claims 2, 7, 19, and 32, which are dependent on Claim 1, are patentable for the same reasons.

Claims 1 and 5 are rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Number 6,290,496 to Azar et al. (herein "Azar"). These claims are novel, however, because Azar fails to teach or suggest the elements recited in the amended claims.

Specifically, like Muller, Azar fails to teach or suggest treating more than one tissue at a time. Azar discloses, with reference to, e.g., FIG. 3, light is emitted through a single window 34 to irradiate only one tissue at a given time. (See Azar Col 8:52-65.) Similarly, as shown in FIG. 9, a "toothbrush like" device 102 includes bristles 109 that are optically coupled to a light guide, but does not disclose irradiating a second tissue. (See Azar Col. 12:54-63.)

Thus, Azar does not anticipate presently amended Claim 1, and Claim 1 is novel and patentable. Similarly, Claim 5, which is dependent on Claim 1, is patentable for the same reasons.

Furthermore, Azar does not anticipate claim 5 by providing multiple spectral bands (as noted by the examiner at page 6) for at least two additional reasons. First, though Azar uses a lamp producing broadband incoherent light, Azar teaches away from using the entire band by disclosing a filter to limit the spectral output. Specifically, Azar states:

The inventors of the present invention have noticed that when irradiated with broad band incoherent light, the stained bacteria within the plaque absorb more light than nearby non stained tissues, leading to a temperature increase of the stained bacteria and to their destruction by coagulation. However, broad band light including light having wavelengths in the range substantially absorbable by oxyhemoglobin may be absorbed by the oxyhemoglobin contained within red blood cells of the blood included in blood vessels. This may lead to undesired photothermal coagulation of blood vessels within the oral cavity. To prevent such undesired blood vessel coagulation the broad band light is preferably filtered to exclude a substantial portion of the light having wavelengths which are substantially absorbed by oxyhemoglobin. *Thus the filtered light is band limited.*

(Azar Col. 5:41-55 (emphasis added).)

Second, Azar does not anticipate Claim 5, because Claim 5 requires "wavelength components in at least two separate spectral bands." Even absent the band limiting filter in Azar, there is no teaching in Azar of a flashlamp output with separate spectral bands.

Claim Rejections - 35 U.S.C. § 103

Claim 6

Claim 6 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Azar in further view of Mendes. The claim, however, is patentable because there is no suggestion or motivation by either reference to provide “at least two sources of radiation emitting different spectral bands of radiation” as required by claim 6. As the examiner notes at page 7, Azar does not “disclose multiple sources for the radiation.” Furthermore, Mendes expressly teaches away from using radiation from different spectral bands. For example, Mendez discloses using a single, narrow band of red light.

Further in accordance with a preferred embodiment of the present invention, the apparatus includes means for concentrating the light of at least one LED and for projecting the light to an oral zone, preferably the gums, for biostimulative treatment thereof, wherein preferentially the light emitted by each of the plurality of diodes has substantially the same wavelength.

(Mendes at 3:17-25.) Further, Mendes teaches that the “exact wavelength of the illumination is confined within a relatively narrow bandwidth.” (Mendes Col. 9:23-25.)

Claim 9

Claim 9 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller. The claim, however, is patentable because there is no suggestion or motivation in Muller to provide the partially etched cladding as claimed.

In support of claim 9, Applicants disclose, for example, a bristle 14 that acts as a waveguide for directing radiation from a radiation source to a portion of a user’s oral cavity. As shown in FIG. 23, a bristle may have a highly refractive core 54 and a low refractive cladding 56. This embodiment allows radiation to be directed to tissue in contact with bristle tip 58. (Application, paragraph 092.) To the contrary, as discussed above, Muller does not disclose a

bristle that prevents radiation from being emitted except when the bristle is in contact with tissue. There is no motivation taught in either reference to combine the claimed element with Muller. Thus, Claim 9 is not obvious.

Claim 21

Claim 21 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of U.S. Patent Number 6,029,303 to Dewan (herein Dewan). The claim, however, is patentable because there is no suggestion or motivation by either reference to combine the references to obtain “a motion sensor and controller which controls the radiation emitter based on signals from the motion sensor” as claimed. Dewan discloses installing a motion detector used as an alert to ensure, for example, sufficiently long brushing by children or the disposal of a toothbrush kept too long. (Dewan Col. 1 40-54.) Dewan does not disclose the use of a motion sensor in conjunction with a control system for controlling a radiation emitter to treat the oral cavity, and there is no motivation expressed to do so in either Dewan or Muller.

Claim 22

Claim 22 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of U.S. Patent Number 5,133,102 to Sakuma (herein Sakuma). (Applicant has presumed that the examiner is referring to U.S. Patent Number 5,133,102, which discloses a toothbrush and not 5,133,120, which is issued to a different inventor and appears to concern other subject matter.) The claim, however, is patentable, because there is no suggestion or motivation by either reference to combine the references to provide a “contact sensor and controller which controls the radiation emitter based on signals from the contact sensor” as claimed. Sakuma discloses a contact sensor for operating an electronic toothbrush that removes plaque by means of an electric current. Neither Muller nor Sakuma provides a suggestion for using a contact sensor in conjunction with a radiation emitter to treat the oral cavity.

Claims 24, 26, 28 and 31

Claims 24, 26, 28 and 31 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of U.S. Patent Number 4,333,197 to Kuris (herein “Kuris”). The

claims, however, are patentable because there is no suggestion or motivation by either reference to provide an apparatus having heat dissipating elements as claimed, such as “one thermally conductive element for extracting heat from the emitter” or a handle acting as a “heatsink” or “a heat transfer element for heating a portion of the oral cavity with waste heat from the apparatus.” The passage from Kuris referred to in the Office Action at page 8 does not disclose a toothbrush having such heat dissipating elements. Rather, Kuris at Col. 4:10-50 discloses a “display case” that houses and charges the ultrasonic toothbrush and has aluminum side walls 38 and 44 for radiating heat. The heat dissipating elements of the display case are not present in the ultrasonic toothbrush itself. Thus, there is no motivation or teaching present in the reference to combine the devices of Kuris and Muller references.

Although Kuris does teach the use of ultrasound, there is no motivation expressed in Kuris or Muller to combine those references to further include “an ultrasound generator for delivering acoustic energy to a target tissue site” in addition to optical or other radiation as claimed in Claim 31. Kuris teaches an improvement to ultrasonic toothbrushes to improve conventional brushing techniques. (Kuris Col. 1:37 – 2:5.) There is no expressed teaching or motivation in either reference to combine those technologies with optical or other therapeutic radiation.

Claims 25 and 27

Claims 25 and 27 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Muller further in view of Kuris and further in view of U.S. Patent Number 6,350,276 to Knowlton (herein “Knowlton”). The claims, however, are patentable because there is no suggestion or motivation by either reference to combine the device of Knowlton with the oral appliances of Muller and Kuris. In fact, Knowlton teaches away from such an application by listing a host of potential applications that do not include treating tissues in the oral cavity. (Knowlton Col. 6:49-57.)

Claim 33

Claim 33 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Muller in further view of U.S. Patent Number 5,658,148 to Neuberger et al. (herein "Neuberger"). The claim, however, is patentable because there is no suggestion or motivation by either reference to provide a drug delivery port as claimed. The water or liquid passage disclosed in Neuberger is used for a different purpose, and there is no teaching or motivation to alter the device of Neuberger or to combine such an altered device with Muller to obtain a drug delivery port that operates using principles consistent with the disclosed operation of the device in Muller. In the specific text cited by the Examiner, Neuberger discloses a passage that delivers water or other liquid under pressure during operation. The purpose of the water or liquid is to facilitate the transfer of radiation, and not to deliver a drug. Neuberger discloses that, when liquid passes over fiber end 53 radiation will pass substantially radiation substantially parallel to the optical fibers due to the change in refractive index. (Neuberger Col. 4:12-25.)

Furthermore, Claims 6, 9, 21, 22, 24-28, 31 and 33 are dependent from Claim 1, and accordingly are patentable for at least the same reasons that Claim 1 is patentable.

CONCLUSION

In summary, the above-identified patent application has been amended and reconsideration is respectfully requested for all the reasons set forth above. In the event that the amendments and remarks are not deemed to overcome the grounds for rejection, the Examiner is kindly requested to telephone the undersigned representative to discuss any remaining issues.

Respectfully submitted,

NUTTER McCLENNEN & FISH LLP

Date: March 29, 2006



Kevin Cronin
Registration No.: 47,203
Attorney for Applicants
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604
Tel: (617) 439-2948
Fax: (617) 310-9948